

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 34813/PCT/02	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/FR2004/000037	International filing date (day/month/year) 09.01.2004	Priority date (day/month/year) 10.01.2003
International Patent Classification (IPC) or national classification and IPC		
Applicant CERAM CONCEPT L.L.C.		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>10</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>																									
<p>4. This report contains indications relating to the following items:</p> <table><tr><td><input checked="" type="checkbox"/></td><td>Box No. I</td><td>Basis of the report</td></tr><tr><td><input checked="" type="checkbox"/></td><td>Box No. II</td><td>Priority</td></tr><tr><td><input type="checkbox"/></td><td>Box No. III</td><td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td></tr><tr><td><input type="checkbox"/></td><td>Box No. IV</td><td>Lack of unity of invention</td></tr><tr><td><input checked="" type="checkbox"/></td><td>Box No. V</td><td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td></tr><tr><td><input checked="" type="checkbox"/></td><td>Box No. VI</td><td>Certain documents cited</td></tr><tr><td><input type="checkbox"/></td><td>Box No. VII</td><td>Certain defects in the international application</td></tr><tr><td><input type="checkbox"/></td><td>Box No. VIII</td><td>Certain observations on the international application</td></tr></table>		<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input checked="" type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input checked="" type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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Date of submission of the demand	Date of completion of this report																								
Name and mailing address of the IPEA/EP	Authorized officer																								
Facsimile No.	Telephone No.																								

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Box No. I

Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-11 _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- nos. 1-10 _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* _____ received by this Authority on _____
- nos.* _____ received by this Authority on _____
- ☒ the drawings:
- sheets 1/8-8/8 _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. II

Priority

1. ☐ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:
- ☐ copy of the earlier application whose priority has been claimed (Rule 66.7(a)).
- ☐ translation of the earlier application whose priority has been claimed (Rule 66.7(b)).
2. ☒ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rule 64.1). Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

The priority of the present application is invalid, since it does not meet the requirements of Article 4C(1), (2) and (4) of the Paris Convention for the Protection of Industrial Property. Document FR-A-2827154, cited as a "P" document in the search report, is regarded as prior art in the sense of PCT Rules 43bis.1 and 64.1.

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims		YES
	Claims	1-10	NO
Inventive step (IS)	Claims		YES
	Claims	1-10	NO
Industrial applicability (IA)	Claims	1-10	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Reference is made to the following documents:

D1: FR-A-2 827 154 (LAZENNEC JEAN YVES)
17 January 2003 (2003-01-17)
D2: EP-A-1 133 958 (DEPUY ORTHOPAED INC)
19 September 2001 (2001-09-19)
D3: EP-A-1 195 149 (HOWMEDICA OSTEONICS CORP)
10 April 2002 (2002-04-10)

1. The application does not meet the requirements of PCT Article 6 because claims 1, 5 and 8 are unclear.

The combination of the first type of insert and the second type of insert in a cotyloid implant is not possible, since they are mutually exclusive alternatives and can be combined in claim 1 only by the conjunction or.

The femoral head mentioned in claims 5, 8 and 10 is not part of the cotyloid implant and cannot form part of the subject matter of the invention.

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
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2. Moreover, despite the lack of clarity mentioned above, the subject matter of claim 1 is not novel (PCT Article 33(2)); consequently, the requirements of PCT Article 33(1) are not satisfied.

Document D1 describes (the references between parentheses refer to that document):

Cotyloid implant (figures 1-10) for hip prostheses, comprising:

- a first type of insert (2, figures 1, 3, 7, 9) that has an inner spherical cavity (2a, figures 1, 7, 9) for accommodating a hemispherical core in such a way that it can move (4, figures 1, 3, 7, 9), said core having an inner cavity (4a, figures 1, 3, 7, 9) which can co-operate in an articulating manner with a femoral head (T, figures 3, 9);
- a second type of insert (3, figures 2, 5, 6, 8, 11, 12) that has an inner cavity (3a, figures 2, 8) which can co-operate in an articulating manner with the femoral head (T, figures 5, 11);

the centre of rotation of the femoral head (T, figures 9, 11) being different from the axis of rotation (x-x', figures 8, 11, 12) of the first type of insert (2, page 7, lines 10-16) and/or of the second type of insert (3, page 7, lines 10-16).

The subject matter of claim 1 thus lacks novelty

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

(PCT Article 33(2)).

3. Dependent claims 2-10 do not contain any features which, in combination with the features of any claim to which they refer, define subject matter that meets the PCT requirements for novelty; see document D1 and the relevant passages of text cited in the search report. The reasons being as follows:

Document D1 also describes (the references between parentheses refer to that document):

- implant (according to claim 2 of the application) with a metal cup (1, page 5, lines 3 and 4, figures 1-12) of hemispherical shape (figures 1-12) for securing in the base of the cotyloid cavity of the iliac bone (page 5, lines 4-6);
- implant (according to claim 3 of the application) in which the cup (1, page 5, lines 3 and 4, figures 1-12) delimits an inner cavity (1a, page 6, lines 13-17, figures 1, 2, 7, 8) that has arrangements for mounting the two types of insert (2, figures 1, 3, 7, 9) and (3, figures 2, 5, 6, 8, 11, 12) as required and in a secure manner;
- implant (according to claim 4 of the application) in which the second type of insert (3, figures 2, 5, 6, 8, 11, 12) and

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Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

- the movable core (4, page 6, line 1, figures 1, 3, 7, 9) comprise arrangements for mounting a ring (5, page 6, lines 1-3, figure 3) for ensuring the holding of the femoral head (T, page 6, lines 1-3, figure 3);
- implant (according to claim 5 of the application) in which the ring (5, page 6, lines 1-5, figures 3, 4) is split (figure 4) so as to be separated by elasticity so as to be positioned in the complementary shaped arrangements in the opening of the insert or of the core (4, page 6, lines 1-5, figure 3), the ring (5, page 6, lines 1-5, figure 3) delimiting an inner concave bearing surface in relation to the outer hemispherical bearing surface of the femoral head (T, page 6, lines 1-5, figure 3);
 - implant (according to claim 6 of the application) in which the arrangements of the inner cavity (1a, page 6, lines 13-17, figures 1, 2, 7, 8) of the cup (1, page 6, lines 13-17, figures 1-12) co-operate with complementary arrangements on the outer surfaces of the two types of insert (2, page 6, lines 13-17, figures 1, 3, 7, 9) and (3, page 6, lines 13-17, figures 2, 5, 6, 8, 11, 12) to ensure securing by clipping (page 6, lines 13-17);
 - implant (according to claim 7 of the

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
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application) in which the arrangements are made up of a series of frusto-conical, circular bearing surfaces (page 6, lines 17-21);

- implant (according to claim 8 of the application) in which the first type of insert (2, figures 1, 3, 7, 9) and the core (4, page 6, line 1, figures 1, 3, 7, 9) are made of ceramic (page 7, line 1), polyethylene (page 7, line 4) or metal (page 7, lines 6-8) and the femoral head (T, figures 3, 9) is made of ceramic or metal (page 3, line 20 and page 7, lines 6-8);
- implant (according to claim 9 of the application) in which the second type of insert (3, figures 2, 5, 6, 8, 11, 12) is made of ceramic (page 7, line 2), metal (page 7, lines 6-8) or polyethylene (page 7, lines 1-3);
- implant (according to claim 10 of the application) in which the first type of insert (2, figures 1, 3, 7, 9), the second type of insert (3, figures 2, 5, 6, 8, 11, 12) and the core (4, page 6, line 1, figures 1, 3, 7, 9) are made of metal (page 3, line 20 and page 7, lines 6-8), polyethylene (page 7, lines 1-3) or ceramic (page 7, lines 1, 2), or a combination of those materials, and the femoral head (T, figures

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3, 9) is made of metal (page 3, line 20 and page 7, lines 6-8) or ceramic, or a combination of those materials.

The subject matter of claims 2-10 thus lacks novelty (PCT Article 33(2)).

4. In addition, the applicant should note that documents D2 and D3 also anticipate the subject matter of claims 1-3 and 6-10; see the relevant passages cited in the search report (see D2, paragraphs 9-11, 17 and 18, the claims and the drawings; D3, paragraphs 13-23, the claims and the drawings).
3. It is noted that:
 - contrary to PCT Rule 5.1(a)(ii), the description does not cite documents D1-D3 and does not indicate the relevant prior art disclosed therein;
 - claim 1 is drafted in the two-part form. Nevertheless, the features should not appear in the characterising part, since they are disclosed in document D1 in combination with the features mentioned in the preamble (PCT Rule 6.3(b)).

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Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

<u>Application No. Patent No.</u>	<u>Publication date (day/month/year)</u>	<u>Filing date (day/month/year)</u>	<u>Priority date (valid claim) (day/month/year)</u>
FR-A-2 827154	17.01.2003	16.07.2001	16.07.2001

2. Non-written disclosures (Rule 70.9)

<u>Kind of non-written disclosure</u>	<u>Date of non-written disclosure (day/month/year)</u>	<u>Date of written disclosure referring to non-written disclosure (day/month/year)</u>
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